

Notice of Allowability

Application No.

10/033,575

Examiner

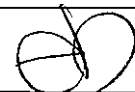
Kaj Olsen

Applicant(s)

LIAMOS ET AL.

Art Unit

1753

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and disclaimer of 12-8-2003.
2. ☒ The allowed claim(s) is/are 23-42.
3. ☒ The drawings filed on 28 December 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

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01/22/04

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Claims 1-22 (canceled)

23. (Previously presented) An operative combination for use in measuring bioanalyte in a sample; the combination comprising:

- (a) a sensor strip; the sensor strip comprising:
 - (i) a substrate having a first end, a second end opposite the first end, a first side edge extending between the first end and second end, and a second side edge, opposite the first side edge and extending between the first end and second end;
 - (A) the substrate first end sized for insertion into an electrical connector;
 - (ii) a sample chamber positioned between the first and second ends;
 - (iii) at least three electrodes on the substrate and in operative contact with the sample chamber, each of the electrodes including a separate electrode trace extending from the sample chamber and along a length of the substrate; and
 - (iv) an insertion monitor stripe on the substrate;
- (b) an electrical connector in electrical communication with a meter, the electrical connector having a sensor strip receiving area sized for operative receipt of the first end of the substrate; the electrical connector further comprising:
 - (i) a first contact structure comprising at least three contact leads, one each of which is positioned to engage one each of three of the at least three electrode traces of the sensor strip when the substrate is operatively positioned with the first end positioned in the sensor strip receiving area of the electrical connector;
 - (ii) a second contact structure comprising at least a first insertion lead and a second insertion lead, each of the first and second insertion leads being

positioned to operatively engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area;

(A) the first insertion lead being positioned with a portion thereof extending across the first side edge of the sensor strip substrate to engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area of the electrical connector; and,

(B) the second insertion lead being positioned with a portion thereof extending across the second side edge of the sensor strip substrate to engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area of the electrical connector;

(c) the sensor strip being removably mounted to the electrical connector with the substrate first end received in the sensor strip receiving area.

24. (Previously presented) An operative combination according to claim 23 wherein:

(a) the insertion monitor stripe extends across the substrate from the first side edge to the second side edge.

25. (Previously presented) An operative combination according to claim 23 wherein:

(a) the substrate has a first end edge adjacent the first end; and

(b) each one of the at least three electrode traces terminates at the first end edge of the substrate first end.

26. (Previously presented) A kit for use in measuring bioanalyte in a sample; the kit comprising:

(a) a sensor strip; the sensor strip comprising:

(i) a substrate having a first end, a second end opposite the first end, a first side edge extending between the first end and second end, and a second

- side edge, opposite the first side edge and extending between the first end and second end;
- (A) the substrate first end sized for insertion into an electrical connector;
- (ii) a sample chamber positioned between the first and second ends;
- (iii) at least three electrodes on the substrate and in operative contact with the sample chamber, each of the electrodes including a separate electrode trace extending from the sample chamber of the substrate; and
- (iv) an insertion monitor stripe on the substrate;
- (b) an electrical connector having a sensor strip receiving area sized for operative receipt therein of the first end of the sensor strip substrate; the electrical connector further comprising:
 - (i) a first contact structure comprising at least three contact leads, one each of which is positioned to engage one each of three of the at least three electrode traces of the sensor strip when the substrate is operatively positioned with the first end positioned in the sensor strip receiving area of the electrical connector;
 - (ii) second contact structure comprising at least a first insertion lead and a second insertion lead, each of the first and second insertion leads being positioned to operatively engage the insertion monitor stripe when the sensor strip first end is operatively positioned in the sensor strip receiving area;
 - (A) the first insertion lead being positioned with a portion thereof extending across the first side edge of the sensor strip substrate to engage the insertion monitor stripe when the first end is operatively positioned in the sensor strip receiving area of the electrical connector; and,
 - (B) the second insertion lead being positioned with a portion thereof extending across the second side edge of the sensor strip substrate to engage the insertion monitor stripe when the first end is

operatively positioned in the sensor strip receiving area of the electrical connector.

27. (Previously presented) A kit according to claim 26 wherein:
- (a) the insertion monitor stripe extends from the first side edge of the substrate to the second side edge of the substrate.
28. (Previously presented) A kit according to claim 27 wherein:
- (a) the sensor strip substrate has a first end edge adjacent the first end, the first end edge extending between the first side edge and the second side edge;
 - (b) each one of the at least three contact leads of the first contact structure is positioned to extend across the first end edge of the sensor strip substrate to engage one of the at least three electrode traces when the sensor strip substrate first end is operatively positioned in the sensor strip receiving area of the electrical connector.
29. (Previously presented) A kit according to claim 27 wherein:
- (a) the sample chamber includes a measurement zone having a volume of no more than 1 μ l.
30. (Previously presented) A kit according to claim 29 wherein:
- (a) the sensor strip is a side-filling sensor strip.
31. (Previously presented) A kit according to claim 27 wherein:
- (a) the sensor strip is a tip-filling sensor strip.
32. (Previously presented) A kit according to claim 27 wherein:
- (a) at least one of the at least three electrodes of the sensor strip is a working electrode covered by a redox mediator.

33. (Previously presented) A kit according to claim 32 wherein:
 - (a) the redox mediator comprises a transition metal complex of osmium.
34. (Previously presented) A kit according to claim 33 wherein:
 - (a) a first one of the at least three electrodes of the sensor strip is positioned opposite to, and facing, a second one of the at least three electrodes of the sensor strip, with the sample chamber positioned therebetween.
35. (Previously presented) A kit according to claim 34 wherein:
 - (a) the first one of the at least three electrodes is separated from the second one of the at least three electrodes by no more than 50 μm .
36. (Previously presented) A kit according to claim 27 wherein:
 - (a) the at least three electrodes of the sensor strip are positioned coplanar with one another.
37. (Previously presented) A kit according to claim 27 wherein:
 - (a) the sensor strip comprises first and second, non-conducting, base substrates;
 - (b) the sample chamber and the at least three electrodes are positioned between the first and second base substrates;
 - (i) one of the at least three electrodes being a reference electrode positioned on one of the first and second, non-conducting, substrates;
 - (A) the reference electrode comprising a conductive carbon electrode; and
 - (ii) a second one of the at least three electrodes is a first working electrode positioned on one of the first and second non-conducting substrates;
 - (A) the first working electrode comprising a conductive carbon electrode; and
 - (iii) a third one of the at least three electrodes is a second working electrode positioned on one of the first and second non-conducting substrates;

- (A) said second working electrode comprising a conductive carbon electrode.

38. (Previously presented) A kit according to claim 37 wherein:
- (a) the electrical connector further comprises a portion of a system that includes a sensor meter having:
 - (i) a component to selectively provide at least one of potential and current to the first contact structure;
 - (ii) a processor to selectively determine analyte concentration from sensor signals received via the electrical connector; and,
 - (iii) a display to selectively show results determined from the sensor signals.
39. (Previously presented) A kit according to claim 37 wherein:
- (a) the insertion monitor stripe is positioned on an opposite side of one of the non-conducting base substrates from the sample chamber.
40. (Currently amended) A method of measuring bioanalyte in a sample; said method including a step of comprising:
- (a) measuring a bioanalyte concentration in a sample, which includes inserting a first end of a sensor strip into a sensor strip receiving area of a electrical connector; the step of inserting including:
 - (i) contacting one each of at least three contact leads in the electrical connector with separate ones of at least three electrode traces on the sensor strip; and
 - (ii) contacting first and second insertion leads of the electrical connector with an insertion monitor stripe on the sensor strip:
 - (A) the step of inserting including positioning the sensor strip so that the first insertion lead extends across a first side edge of the sensor strip to engage the insertion monitor stripe; and

- (B) the step of inserting including positioning the sensor strip so that the second insertion lead extends across a second side edge of the sensor strip to engage the insertion monitor strip, the second side edge being an edge opposite the first side edge.

- 41. (Previously presented) A method according to claim 40 wherein:
 - (a) the step of inserting includes positioning the sensor strip so that each one of three contact leads in the electrical connector extends across a first end edge of the sensor strip, to engage a respective electrode trace;
 - (i) the first end edge extending between the first and second side edges.
- 42. (Previously presented) A method according to claim 40 wherein:
 - (a) the step of inserting includes inserting a first end of a sensor strip which includes, in a portion of the sensor strip other than the first end, a sample chamber including blood therein.